

FDA Dermatologic and Ophthalmic Advisory Committee Meeting

September 18- 19th, 2000

Issues for Advisory Committee

- **Day 1**
 - FDA and Risk Management

 - Pregnancy Exposure
 - Agency concerns: continuing pregnancy exposures
 - Pregnancy Prevention Program

Accutane Advisory Committee

- Day 2
 - Psychiatric Events
 - New Formulation Isotretinoin New Drug Application

Risk Management

- FDA Concerns: Ensuring Safe Use
 - Known risks are managed or prevented
 - Teratogenic risks
 - Voluntary PPP
 - Uncertain risks
 - Psychiatric adverse events associated with the use of Accutane

Opportunities For Improvement

- **Risk Management Options: Known Risks**
 - Goals of Risk Management Program for PPP
 - Elements considered essential by FDA
- **Risk Management and Assessment Options for Uncertain Risk**
 - Goals to minimize risk
 - Possible elements : education/information, further study